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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,681	03/30/2000	Hans Berg Andreasen		3146

7590 09/04/2003

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EXAMINER	
OH, SIMON J	

ART UNIT	PAPER NUMBER
1615	15

DATE MAILED: 09/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/509,681	ANDREASEN ET AL.	
	Examiner	Art Unit	
	Simon J. Oh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's amendment and response, both received on 11 June 2003.

Claim Objections

The objection to Claims 4-8, 10, and 13-15 under 37 CFR 1.75(c) as being in improper form because of multiple claim dependency is hereby withdrawn.

Claim Rejections - 35 USC § 101 and 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of Claims 15 and 16 under 35 U.S.C. 101 and 112 is maintained.

Claim 31-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 31-33 provide for the use of an iron-dextran compound, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 31-33 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-16 under 35 U.S.C. 103(a) over Usher *et al.* is maintained.

The rejection of Claims 8 and 14 under 35 U.S.C. 103(a) over Usher *et al.* and Mioduszewski *et al.* is maintained.

Claims 17-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Usher *et al.*

The Usher *et al.* patent teaches dextran ferric hydroxide complexes made by a process set forth from Column 2, Line 44 to Column 3, Line 53; as well as Examples 1-7. Briefly, a dextran having a molecular weight of 1,200 to 6,000 Daltons is hydrogenated by sodium borohydride (U.S. Patent No. 3,234,209 is incorporated into Usher *et al.* by reference) to convert terminal

aldehyde groups into alcohol groups. A compound such as sodium hypochlorite is then used to oxidize the dextran. The iron complex is then formed by reacting the dextran with purified ferric hydroxide or ferric salt (See Column 29, Lines 35-39), at a pH of 6.0 to 8.7 while heating above 100°C. The complex is then purified by filtration through a 0.45-micron filter. Conversion of the ferric hydroxide into ferric oxyhydroxide is not specifically set forth in the Usher *et al.* patent. However, since the formulation is heated in the same manner as the instant claims, it appears that the resultant iron-dextran complex is not critically different, in the absence of data. It also appears that the pH is not critical with regards to the instant Claim 7 and any claims dependent thereon, except for conversion of the ferric salt and formation of the iron-dextran complex, which is disclosed in the reference. Accordingly, absent a demonstration of criticality thereto, adjustment of the pH to a value greater than 10 does not appear to be critical. The Usher *et al.* patent also teaches that the resultant complexes are stable since a molecular weight from 1,200 to 6,000 is provided. Accordingly, inclusion of the optional hydroxy acid salt such as citrate or gluconate does not appear to be critical. The Usher *et al.* patent does not specifically teach hydrogenation where at the most 15% by weight reducing sugar and dextran is subsequently subjected to oxidation. However, the reference teaches that the resultant dextran has terminal aldehyde groups converted into alcohol groups and that the product is stable since the molecular weight ranges from 1,200 to 6,000 Daltons. Accordingly, this limitation does not appear to be critical in the absence of data.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Usher *et al.* in view of Mioduszewski *et al.*

The relevant portions of the Usher *et al.* patent are detailed in the above rejection of Claims 17-33 under 35 U.S.C. 103.

The Usher *et al.* patent does not teach the inclusion of an organic hydroxy acid salt such as a citrate or gluconate.

The Mioduszewski *et al.* patent teaches iron-dextran complexes with citric acid or sodium citrate, stating that inclusion of the organic hydroxy acid salt imparts greater stability during sterilization and during long time storage.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to combine the teachings of Mioduszewski *et al.* and Usher *et al.* with the motivation of increasing stability of the iron-dextran complex during sterilization and long time storage.

Double Patenting

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 9, 11, and 16 under 35 U.S.C. 101 as claiming the same invention as that of Claims 17, 24, and 26 in co-pending Application No. 10/300,032 is maintained.

The rejection of Claims 1-16 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-18 of U.S. Patent No. 6,291,440 is maintained.

The provisional rejection of Claims 1-8, 10, and 12-15 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 18-23 and 25 in co-pending Application No. 10/300,032 is maintained.

Claims 17 and 19-23 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of Claims 18-23 of copending Application No. 10/300,032. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim 18 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 19 of co-pending Application No. 10/300,032. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 18 in the instant application is the genus of the scope of the species encompassed by the language of Claim 19 in Application No. 10/300,032.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed 11 June 2003 have been fully considered but they are not persuasive.

Regarding the previously set forth rejection of Claims 15 and 16 under both 35 U.S.C. 101 and 112, the applicant has amended these claims to recite what the applicant deems to be active positive steps. However, the fact that they remain use claims means that these claims

remain in improper form for method or process claims. At the very least, these claims remain non-statutory under 35 U.S.C. 101. See MPEP § 2173.05(q). The examiner urges the applicant to either cancel the claims or amend them to properly recite processes or methods of preparation. In any case, Claims 15 and 16 remain rejected under both 35 U.S.C. 101 and 112.

Regarding the applicant's arguments concerning the double patenting rejections that were previously set forth, there appears to be a bit of confusion arising from the applicant's response. The examiner directs the applicant's attention to the middle portion of Page 11 of the applicant's response, in which it is stated that the abandonment of Application No. 10/300,032 is contingent upon the withdrawal of the restriction requirement of 19 September 2003. The first paragraph of the previous Office Action, that restriction requirement of 19 September 2002 was withdrawn, and is in fact acknowledged by the applicant near the middle of Page 7 of the applicant's response.

Next, the examiner would like to point out to the applicant that so long as the claims in U.S. Application Serial No. 10/300,032 are still pending, any applicable double patenting rejections previously set forth must stand. Such rejections can never be withdrawn simply because the applicant has notified the examiner in advance that the applicant plans to allow the co-pending application to go abandoned. The applicant also has the option of expressly abandoning the co-pending application, but has not done so.

Regarding the applicant's arguments concerning the prior art rejections of record, it is the position of the examiner that the applicant's arguments require a narrow interpretation of both the claims and the prior art. It is the position of the examiner that one of ordinary skill in the art, giving both the prior art and the claims in their present form their broadest reasonable

interpretation, would find the claimed invention obvious in view of the prior art. See MPEP § 2111 and 2123.

The applicant's arguments appear to be based on an overly stringent requirement, approaching that of anticipation, when the rejections of record are based upon obviousness. That is, would one of ordinary skill in the art, having knowledge of the processes of the prior art, be able to obtain the processes and compositions claimed by the applicant in the instant application through a reasonable amount of routine experimentation that would be obvious and have a reasonable chance of success? It is the position of the examiner that this is the case. Despite the applicant's contrast of the properties of the instantly claimed invention and that of the collective disclosure of the prior art, it is the position of the examiner that by using the basic steps of the process of the prior art, one of ordinary skill in the art could obtain the instantly claimed invention with a reasonable expectation of success. The applicant has not set forth a persuasive argument that, despite the similarities of the process disclosed in the instant application and the process disclosed in the prior art, "in no way would a skilled artisan arrive at the present invention".

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh
Examiner
Art Unit 1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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